

Merck Sharp & Dohme Corp.
UG2A-70
351 N Sumneytown Pike
PO Box 1000
North Wales PA 19454-2505



March 4, 2011

Subject: Foradil® Aerolizer® (formoterol fumarate inhalation powder)

Blister cards containing Foradil capsules are no longer packaged in aluminum pouch

Dear Pharmacist:

This letter is to inform you of a print error in the Medication Guide which is packaged with Foradil® Aerolizer®. The Medication Guide states that there is an aluminum foil pouch covering the foil blister cards. Please be advised that Novartis, the manufacturer and packager of this product has stopped providing the blister cards within the aluminum foil pouch. However, the aluminum foil pouch is still referenced in the Medication Guide.

Novartis received approval from the US Food and Drug Administration in 2007 to remove the use of the aluminum foil pouch but has continued to supply the blister cards in this packaging until 2010 when the change went into effect and was implemented. Please be assured that the quality of this product is not affected by the discontinued use of this aluminum foil pouch.

Novartis has received approval from FDA for the updated labeling and the Medication Guide is currently being revised to remove all reference to the aluminum foil pouch. To assure that supplies of Foradil Aerolizer continue to be made available for our patients, current labels will be used for a short period with the full knowledge and agreement of FDA.

Please note that this update to the Medication Guide section is only to remove reference to the aluminum foil pouch covering the blister cards. The patient directions “CAPSULES SHOULD ALWAYS BE STORED IN THE BLISTER AND ONLY REMOVED FROM THE BLISTER IMMEDIATELY BEFORE USE” is unchanged and remains in effect.

The only action required on your part is to advise patients when dispensing this medication that the blister packs are no longer provided with the aluminum foil overwrap, and that the manufacturer has provided assurance that product quality is not affected. The directions to patients regarding opening of the blister packs, removal of the capsules from the blister packs, and placement of the capsule in the inhalation device are not changed nor has the use of the product changed. Other than advising patients that there is no aluminum foil pouch, no further action is required on your part. In those cases where patients may wish to contact the distributor,

please provide this number Merck National Service Center: 1- 800-NSC-MERCK. This notification applies to the following Foradil Aerolizer NDC numbers:

Unit Dose (Blister Pack)

Box of 12 (strips of 6) NDC 0085-1402-01

Unit Dosage (Blister Pack)

Box of 60 (strips of 6) NDC 0085-1401-01

Please see accompanying full Prescribing Information for FORADIL, including the Boxed Warning about asthma-related death.

Sincerely,

A handwritten signature in cursive script that reads "S. Sethu K. Reddy".

S. Sethu Reddy, MD, MBA, FRCPC, FACP, MACE
Vice President
Head - US Medical Affairs, Merck & Co., Inc.
351 N. Sumneytown Pike, North Wales, PA, 19454